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(58) Field of search  
A5B

(54) **Dimethyl phthalate preparations**

(57) Topical preparations for the treatment of chilblains and the related inflammatory conditions of skin chaffing in cold weather and pressure sores on the human body comprises dimethyl phthalate and a carrier such as a liquid e.g. ethanol or dimethylsulphoxide, an aqueous cream or an aerosol propellant composition.

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## SPECIFICATION

## Treatment of chilblains

5 This invention relates to the treatment of chilblains and the related inflammatory conditions of chaffing in cold weather and pressure sores on the human body.

There are pharmaceutical preparations known for the treatment of chilblains and related inflammatory conditions, but I have discovered a method of treatment that is more efficacious while it does not involve the use of expensive materials.

Accordingly the present invention provides a method for the treatment of chilblains and the related inflammatory conditions of skin chaffing in cold weather and pressure sores on the human body, which method comprises the topical application of dimethyl phthalate to the afflicted parts of the body.

The invention also provides dimethyl phthalate for use in a method for the topical treatment of chilblains and the related inflammatory conditions of skin chaffing in cold weather and pressure sores on the human body.

The dimethyl phthalate is preferably used in a topical preparation containing a pharmaceutically acceptable carrier. The carrier may typically consist of a liquid to ensure good penetration of the dimethyl phthalate into the desired part of the skin, and such a carrier includes dimethyl sulphoxide or ethanol.

Another typical carrier consists of a propellant composition for application of dimethyl phthalate in an aerosol spray. A particularly suitable carrier is an aqueous cream of the well known type.

Preferably such compositions contain 5-95% by volume of dimethyl phthalate, especially about 30% by volume. The composition is applied to the chilblains or related inflamed area as required until relief is secured from the usual pain and irritation.

In a double blind cross-over study an aqueous cream was used and it contained 30% by volume of dimethyl phthalate. Comparison was made with a commercial local anaesthetic and antipuritic cream that is currently used in the treatment of chilblains. Subjects suffering from chilblains applied the dimethyl phthalate or commercial cream for 3-4 days, followed by placebo cream for 3-4 days; or placebo cream was used, followed by one of the other creams. Subjects were examined before treatment started and the severity and duration of their chilblains was scored and they were then examined after each period of treatment. At the post treatment examination the subjects were asked to estimate the maximum degree of relief secured.

The results of the trial were analysed in the usual way. A significant number of subjects secured relief with the dimethyl phthalate cream in comparison with the commercial cream and the placebo.

The following Examples illustrate the preparation of compositions containing dimethyl phthalate for use in accordance with the invention.

*Example 1*

A 20% by volume solution of dimethyl phthalate in

ethanol was prepared by mixing the two components. It was suitable for direct topical use.

*Example 2*

A 30% by volume solution of dimethyl phthalate in dimethyl sulphoxide was prepared by mixing the two components. It was suitable for direct topical use.

*Example 3*

An aqueous cream B.P. was prepared in the usual way. To one portion 10% by volume was added of dimethyl phthalate and to another 30% by volume was added. Again these preparations were suitable for direct topical application.

## 75 CLAIMS

1. A method for the treatment of chilblains and the related inflammatory conditions of skin chaffing in cold weather and pressure sores on the human body, which method comprises the topical application of dimethyl phthalate to the afflicted parts of the body.

2. A method as claimed in claim 1, wherein the dimethyl phthalate is applied in combination with a pharmaceutically acceptable carrier.

3. A method as claimed in claim 2, wherein the pharmaceutically acceptable carrier is a liquid, an aqueous cream or an aerosol propellant.

4. A method as claimed in claim 3, wherein the liquid is dimethyl sulphoxide or ethanol.

5. A topical pharmaceutical preparation for the treatment of chilblains and the related inflammatory conditions of skin chaffing in cold weather and pressure sores on the human body, which preparation comprises dimethyl phthalate together with a pharmaceutically acceptable carrier.

6. A topical preparation as claimed in claim 5, wherein the carrier is a liquid, an aqueous cream or an aerosol propellant composition.

7. A topical preparation as claimed in claim 6, wherein the liquid is dimethyl sulphoxide or ethanol.

8. A topical pharmaceutical preparations as claimed in any one of claims 5 to 7, which preparation comprises about 5 to 95% by volume of dimethyl phthalate.

9. A topical pharmaceutical preparation as claimed in claim 8, wherein the preparation comprises about 30% by volume of dimethyl phthalate.

10. A topical pharmaceutical preparation as claimed in claim 6 substantially as described with reference to any one of Examples 1 to 3.

11. Use of dimethyl phthalate in a method for the topical treatment of chilblains and the related inflammatory conditions of skin chaffing in cold weather and pressure sores on the human body.

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